1 MANAGEMENT AND LEADERSHIP

OVERVIEW OF MANAGEMENT AND LEADERSHIP

Effective management of a practice begins with understanding the various responsibilities and authorities of individuals in the practice, and how these individuals work together. The practice manager ensures that policies and procedures appropriate to the various teams within the practice are developed and implemented. The responsibilities of the practice manager are documented and are known to the practice personnel.

Documents prepared by each team define their goals and identify current and planned services. The lines of communication for achieving these goals are represented on an organisational chart.
Effective leadership is essential for the practice to be able to operate efficiently, achieve its goals and fulfil its mission.

It is important that the practice team has identified leaders in areas such as clinical care, information management, complaints/patient feedback and human resources. It is possible that a single individual within the practice may assume all these leadership responsibilities. In some practices, however, leadership will be undertaken by different members of the practice team, although leadership of clinical care should remain the responsibility of a principal Medical Practitioner.

Standards

1.1 Mission statement

1.1.1 The practice's clinical and managerial leaders are identified and are collectively responsible for defining the practice's mission and creating the plans and policies needed to fulfil the mission.

Standard Intent:
A practice's mission statement usually reflects the needs of its patient population and patient care services are designed and planned to respond to those needs.
It is important that all members of the practice team are recognised and included in the process of defining the practice's mission.
Effective leadership is essential for a practice to be able to operate efficiently and fulfil its mission. Leadership is provided by individuals working together or separately, and can be provided by any number of individuals.
The radiology and diagnostic imaging services are planned and designed to respond to the needs of the patient population. The leaders of the practice determine what imaging services are essential to the community, ideally in collaboration with the community, as well as the scope and intensity of these services.
A strategic plan outlining the proposed development of the practice over the coming year is a useful tool to support the practice in achieving its mission and meeting identified patient needs. To ensure effective implementation, the plan should be revisited regularly throughout the year to document progress against agreed, predetermined, time-bound targets. The practice's strategic plan should be reviewed yearly to ensure that it remains reflective of the current needs of the practice population.

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Criteria

1.1.1.1 The leaders of the service are formally or informally identified.

1.1.1.2 The practice has a mission statement that reflects the strategic objectives of the practice and matches the needs of the community served by the practice.

1.1.1.3 The leaders are collectively responsible for ensuring that the mission statement is known to all personnel, patients, carers and the community served.

1.1.1.4 The leaders, in liaison with the whole practice team co-ordinates the compilation of an annual strategic plan and budget.

1.1.1.5 The leaders are collectively responsible for implementing the practice's mission and strategic plan.

1.1.1.6 The strategic plan is reviewed on an annual basis.

1.1.1.7 Regular monitoring of the implementation of the strategic plan against envisaged timeframes is documented at intervals determined by the practice, but at least quarterly.

1.1.1.8 Progress in achieving the objectives of the strategic plan is reviewed regularly throughout the year at a frequency determined by the practice.

1.1.1.9 Where appropriate, the leadership roles in various positions are documented, agreed to and known by the personnel.

1.1.1.10 The health facility manager promotes networking with the leaders of other relevant organisations in the community.

1.1.1.11 There is evidence of interaction with Community Health Committee members.

1.2 Management systems

1.2.1 A manager is responsible for operating the practice within relevant laws and regulations.

Standard Intent:
The practice manager is appointed to be responsible for the overall, day-to-day operation of the practice. These responsibilities are documented and known to the practice personnel. The practice manager is responsible for promoting and monitoring the implementation of the policy and procedure framework of the practice.

1.1.1 Criteria

1.2.1.1 The manager is responsible for the day-to-day running of the practice.

1.2.1.2 The manager has the education and/or experience necessary to carry out his or her responsibilities.

1.2.1.3 The manager ensures that there is a system in place to monitor the implementation of applicable laws and regulations.

1.2.1.4 There is evidence of response to any reports from inspecting and regulatory authorities.

1.2.1.5 The manager implements processes to manage and control human, financial and other resources.

1.2.1.6 The manager promotes networking with other individuals and leaders of relevant practices in the community.

1.2.1.7 There is a current budget for the practice.

1.2.2 The practice facilitates communication between teams and individuals within the practice and with referral services.

Standard Intent:
The leaders develop a culture that emphasises co-operation and communication. Relevant personnel members become part of the communication network.

Criteria

1.2.2.1 The leaders facilitate communication between teams where relevant and between individual personnel members.

1.2.2.2 Agendas are prepared for meetings in order to allow those attending to prepare for participation.

1.2.2.3 Minutes of meetings are taken and are circulated to all relevant personnel.

1.2.2.4 There is a procedure to make sure that important matters resulting from management meetings are communicated to and acted upon by personnel.

1.2.2.5 The lines of communication between the practice and referral services are clearly defined.

1.2.2.6 Relations are established and contact maintained with other relevant services and agencies, including both governmental and non-governmental agencies.

1.2.2.7 The service is organised to provide a safe and effective service and is co-ordinated with other relevant services in the referral hospital and in the community.

1.3 Policies and procedures

1.3.1 The practice manager ensures that policies and procedures which support the activities of the practice are implemented.

Standard Intent:
The practice manager ensures that all policies which apply to each team within the practice are available to the personnel and that they are implemented and monitored. These policies should include as a minimum:

a) policies and procedures regarding governance;
b) registration and licensing of personnel;
c) radiation safety and optimised radiation technique chart;
d) diagnostic imaging equipment and servicing;
e) healthcare associated infection policies and procedures;
f) provision of diagnostic imaging services and reporting and recording image findings policies;
g) patient consent and information policies;
h) patient identification and procedure matching policies;
i) medication management policies;
j) diagnostic imaging protocols;
k) patient feedback and complaints policies.

1.3.1 Criteria

1.3.1.1 Policies and procedures that guide and support the imaging services offered by the practice are implemented.

1.3.1.2 Policies and procedures are signed and dated by persons authorised to do so.

1.3.1.3 Policies and procedures are correctly indexed and filed.

1.3.1.4 Each policy and procedure is reviewed when indicated and then dated and signed.

1.3.1.5 There is a process to ensure that personnel are familiar with relevant policies and procedures.

1.4 Human Resources

1.4.1 There is a plan for the provision of adequate numbers of suitably qualified personnel

Standard Intent:
The leaders of the practice define the desired qualifications, skills, knowledge and any other requirements as part of projecting personnel complements and needs.
Personnel retention rather than recruitment provides greater long-term benefit. Retention is increased when leaders support personnel development. It is therefore advisable for the practice to plan and implement uniform programmes and processes related to the recruitment, retention and development of all personnel.
The practice has a written plan which identifies the numbers and types of personnel required and the skills, knowledge and other requirements needed in each team.
The planning process includes

- Personnel recruitment
- Numbers and categories of personnel required
- Desired education, qualifications, skills and knowledge
- Assignment and reassignment of personnel
- Personal development of personnel
- Personnel retention

1.4.1 Criteria

1.4.1.1 There are documented processes for staffing the practice.

1.4.1.2 The desired education, qualifications, skills and knowledge are defined for personnel members.

1.4.1.3 Personnel employed by the practice are managed in terms of the employer's policies and procedures relating to job descriptions, orientation and induction.

1.4.2 There is an effective process for gathering, verifying and evaluating the credentials (registration, education, training and experience) of those health care professionals who are permitted to practice independently.

Standard Intent:
The practice needs to ensure that it has qualified health professional personnel who appropriately match its mission, resources and patient needs.

An individual's credentials consist of an appropriate current registration, evidence of completion of professional education and any additional training and experience. There is a process for gathering this information and verifying its accuracy. The process applies to all clinical practitioners employed by the practice, including locums. Evaluating an individual's credentials is the basis for two decisions: whether this individual can contribute to fulfilling the practice mission and meeting patient needs and if so, what clinical services this individual is qualified to perform.

These two decisions are documented and the latter decision is the basis for evaluating the individual's ongoing performance.

Criteria

1.4.2.1 There is a reliable, documented process for evaluating and verifying the credentials (license, education, training and experience) of physicians.

1.4.2.2 There is a reliable, documented process for evaluating and verifying the credentials (license, education, training and experience) of health professionals.

1.4.2.3 Personnel files contain copies of qualifications and licenses/registration from the relevant authority for all health professionals.

1.4.2.4 The registration, education, training and experience of these individuals are documented and have been verified by the appropriate registration body.

1.4.2.5 A determination is made about the annual registration of the individual to provide patient care services.

1.4.2.6 All personnel members with direct contact with the public have had a police check, a copy of which is kept in their personnel file. Police checks are repeated every 3 years/as appropriate.

1.4.3 Clinical and administrative personnel participate in continuing education, research and other educational experiences to acquire new skills and

knowledge and to support job advancement.

Standard Intent:
The practice supports opportunities for continuing education and training of personnel to ensure they remain up to date with current best practice and to acquire advanced or new skills. These opportunities may be offered by the practice, by a professional association or through educational programmes in the community. The practice supports such opportunities as appropriate to its mission and resources. Such support may be given through tuition support, scheduled time away from work, recognition for achievement and in other ways.

Criteria

1.4.3.1 The practice supports continuing education for its clinical personnel and maintains records of this in personnel files.

1.4.3.2 There is a development strategy for the practice that ensures that the practice manager and administrative personnel receive the training required to fulfil their responsibilities.

1.4.3.3 Personnel members are informed of opportunities to participate in advanced education, training, research, and other experiences.

1.5 Finances

1.5.1 The practice manager is responsible for the implementation and maintenance of a financial strategy.

Standard Intent:
Financial planning and management need to be conducted by a person who is suitably qualified or skilled and experienced in all matters relating to the finances of the practice. Clinical and managerial personnel both need to be included in planning the financial requirements of the practice. They require information relating to the funds available to them for the management of the practice and up-to-date statements of current expenditure.
Sound accounting and auditing practices are implemented to ensure transparency. These practices are guided by documented policies and procedures. The practice manager ensures that these policies and procedures are implemented.

1.6.1 Criteria

1.5.1.1 A designated person is responsible for the implementation and maintenance of a financial strategy.

1.5.1.2 This person is suitably qualified and/or experienced in accounting and financial management.

1.5.1.3 The responsibilities of this person include ensuring that policies and procedures for all functions are implemented.

1.5.2 Budgeting and reporting processes are consistent with statutory requirements and accepted standards.

1.5.2 Criteria

1.5.2.1 There is a current budget for the organisation.

1.5.2.2 A report is produced at least quarterly for the owners of the practice, setting out the financial position to date.

1.5.2.3 There is a mechanism for establishing the reason for budget variation in either income or expenditure.

1.5.2.4 Capital investment proposals are subject to unanimous agreement among the partners or are agreed according to a voting system acceptable to all partners in the practice.

1.5.3 The practice provides patient services in line with accepted business, financial, ethical and where relevant legal standards.

Standard Intent:
The practice has ethical and legal responsibilities to its patients, personnel and the wider community. The leaders understand these responsibilities as they apply to the business and clinical activities of the practice.

Criteria

1.5.3.1 The practice has documented ethical and legal policies and procedures for the management of the practice.

1.5.3.2 Referral and request forms, letterhead, administrative records and other official documents are accessible only to authorised persons.

1.5.3.3 Internal and external financial audit systems which meet audit requirements are maintained.

1.5.3.4 Where required, annual audited financial statements are produced within the required time frame.

1.5.3.5 There is a capital asset register, which is routinely maintained.

1.5.3.6 Assets are insured.

1.5.3.7 All health professionals provide evidence of professional indemnity insurance. MOH feedback.

1.6 Supply Chain Management

1.6.1 There is an effective system to ensure that equipment and supplies are ordered, stored and distributed.

Standard Intent:
A competent person ensures that equipment and supplies are ordered timeously, stored safely and distributed appropriately.
Policies and procedures are developed for the various provisioning functions. Such policies should include as a minimum:

- Ordering of and payment for supplies and equipment
- Safe storage of supplies
- Condemning procedures
- Security of order books, prescription pads and other face-value documents
- Condemning of equipment

The organisation needs to ensure that appropriate control measures are in place and that finances are made available for the purchase of those items of equipment and supplies which have been identified as being required by clinical and managerial personnel.

1.3.1 Criteria

1.6.1.1 An individual is designated to control the ordering, storage, distribution and control of equipment and supplies used in the organisation.

1.6.1.2 Policies and procedures relating to all aspects of provisioning/supply chain management as discussed in the intent statement above are implemented.

1.6.1.3 Secure storage facilities are available.

1.6.1.4 Prescription pads, letterhead, administrative records and other official documents are accessible only to authorised persons.

1.7 Risk management

1.7.1 The practice manager and personnel work collaboratively to develop, implement and maintain effective risk management systems in the practice.

Standard Intent:
To plan effectively, the practice must be aware of all relevant risks. The goal is to prevent accidents and injuries, maintain safe and secure conditions for patients, families and personnel and reduce and control hazards and risks. Risk management includes:

- Comprehensive risk assessment of the practice
- Designing all aspects of the risk management plan (financial, physical, environmental, medico-legal, operational etc.)
- Implementation of the programme
- Personnel education
- Testing and monitoring the programme
- Periodic review and revision of the programme

Monitoring of all aspects of the programme provides valuable data to make improvements in the programme and further reduce risks within the practice.

Criteria

There are documented risk management processes for identifying all risks (physical, environmental, medico-legal, operational, etc.) relating to organisational processes and systems, personnel, patients, visitors to the practice and physical facilities.

1.7.1.1 There are documented risk management processes for identifying all risks (physical, environmental, medico-legal, operational, etc.) relating to organisational processes and systems, personnel, patients, visitors to the practice and physical facilities.

1.7.1.2 The practice manager ensures the development and implementation of

written policies and procedures for risk management processes and activities.

1.7.1.3 A nominated individual with relevant qualifications, skills and/or experience supervises the implementation of the risk management system.

1.7.1.4 Ongoing in-service training of all personnel in these policies, procedures and risk management principles is documented.

1.7.1.5 Risk management systems are reviewed whenever there are changes in organisational systems and processes or physical facilities.

1.7.2 The practice designs and implements a co-ordinated programme to reduce the risk of infections in patients and healthcare workers.

Standard Intent:
For an infection prevention and control programme to be effective, it must be comprehensive, encompassing both patient care and employee health. The programme is appropriate to the size and geographic location of the practice, the services offered by the practice and the patients seen by the practice.

Infections can enter the practice via patients, their families, personnel, visitors, other individuals and vectors. Thus, all areas of the practice where these individuals or vectors are found must be included in the programme of infection surveillance, prevention and control.
Certain infections require patients suffering from these infections to be isolated from non-infected patients, such as patients with TB or high risk influenza. These patients are identified when requesting an appointment and appropriately triaged. If it is necessary for these patients to attend the surgery, they are directed to a separate waiting area to prevent transmission of the infection to non-infected patients.
The programme is managed by a nominated individual within the practice and all practice personnel are informed of the nomination. Their qualifications depend on the activities they will carry out and may be met through education, training and experience. Co-ordination involves communication with all parts of the practice to ensure that the programme is continuous and proactive.
Whatever the mechanism chosen by the practice to co-ordinate the infection control programme, medical and nursing personnel are represented and engaged in the activities. The individual, committee, or other mechanism must also monitor those support services in the practice which may lead to the spread of infection, e.g. cleaning and waste disposal.
Hand washing and disinfecting agents are fundamental to infection prevention and control. Soap and disinfectants are located in those areas where hand washing and disinfecting procedures are required. Personnel are educated in proper hand washing and disinfecting procedures.

Criteria

1.7.2.1 A nominated individual is responsible for infection control in the practice and practice personnel are aware of the nomination.

1.7.2.2 Written policies and procedures guide personnel in the implementation of the infection control programme.

1.7.2.3 All patient and personnel areas of the practice are included in the documented infection control programme.

1.7.2.4 Regular in-service training is given to all personnel in the field of infection control and is documented.

1.7.2.5 Infection control is on the agenda of all personnel meetings of the practice and discussion points are documented.

1.7.2.6 Hand washing and disinfecting facilities, including water, soap, paper towels or hand sanitizers are available in all relevant areas.

1.7.2.7 Personnel are constantly reminded of the importance of effective hand washing, e.g. posters are displayed.

1.7.2.8 The practice reports on notifiable diseases to appropriate external public health agencies.

1.7.2.9 A nominated individual has been trained in and is responsible for sterilization procedures within the practice, where applicable and can describe the process in detail.

1.7.2.10 Relevant personnel members are immunised against Hep B according to practice policy.

1.7.2.11 There is a documented policy for the management of exposure to high risk infections, e.g. needle-stick injuries.

1.7.2.12 Post exposure prophylaxis is available to personnel in accordance with national policy and includes the management of the patient from whom the needle was withdrawn.

1.7.2.13 There is a documented policy for the management of body fluid spills.

1.7.2.14 There is a documented policy for the triage of patients with potential communicable diseases.

1.7.3 The practice has a written policy which takes into account the need for infection control procedures relating to the handling, storing and disposing of both clinical and radioactive waste.

Standard Intent:
Protocols need to be developed to guide personnel in ensuring their own safety, the safety of others and the safety of the environment when implementing waste removal systems.

Household waste, hazardous wastes (such as chemicals and hazardous gases), pharmaceutical and healthcare waste are identified by the practice and are safely controlled in accordance with a written policy. All healthcare waste is regarded as hazardous or potentially hazardous. The policy is included in the practice's risk management plan.

Criteria

1.7.3.1 The practice has a waste management policy that includes the safe

handling, storing and disposing of all different types of waste.

1.7.3.2 The policies are consistent with current local by laws and regulations.

1.7.3.3 The policy makes provision for the appropriate management of confidential waste.

1.7.3.4 Waste is segregated in accordance with policies, procedures, municipal by-laws and regulations.

1.7.3.5 The colour of bag and type of container appropriate to the type of waste generated are available.

1.7.3.6 Waste is protected from theft, vandalism or scavenging by animals.

1.7.3.7 Waste is collected at appropriate times so that hazards are not caused.

1.7.3.8 There is documented evidence of radioactive waste disposal which includes the date of disposal, the radioisotope including the half-life, the quantity of radioisotope disposed of and the method of disposal.

1.7.4 The practice has a documented policy for formal review of adverse events within the practice.

Standard Intent
As a minimum, the practice should have a system for recording, analysing, discussing and learning from adverse events within the practice. This should include clinical, managerial, administrative and all other adverse events. The data collected, analysis of the data, discussions surrounding the event, decisions based on the discussions and any suggested changes should be documented and kept on file. A nominated personnel member must be responsible for this process and for the implementation, monitoring and review of the changes. This ensures that the organisation learns from its mistakes and prevents recurrence of the same mistakes, thereby providing continuous improvement in service delivery. Lessons learned could be shared with other practices to provide benchmarking.

Clinically significant events such as medication errors, e.g. prescribing a drug to a patient when the records indicate that the patient is allergic to the drug, should always precipitate intense analysis to understand the cause and prevent recurrence.

All records relating to these discussions should be anonymised.

Criteria

1.7.4.1 A documented procedure for the monitoring of negative incidents/near misses/ adverse (sentinel) events is available, which includes the documentation of interventions and responses to recorded incidents.

1.7.4.2 Formal significant event analyses are undertaken when necessary.

1.7.4.3 Notes are kept regarding the data analysis and actions arising from the review.

1.7.4.4 Any change suggested as a result of these case reviews are documented as policies/plans/procedures.

1.7.4.5 The implementation of these new policies/plans/procedures is delegated to a nominated individual who is responsible for monitoring the effectiveness of the changes and arranging reviews if appropriate.

1.7.4.6 Where relevant, there are documented quality improvement activities, which describe the actions taken in response to incidents related to medication management.

1.7.4.7 There is a documented policy for reporting, investigating, and responding to patient care mismatching events when they occur and implementing changes, where relevant, to reduce the risk of future incidents.

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1.7.5 The practice makes provision for the safety and security of personnel, visitors, patients and facilities.

Standard Intent:
Consideration is given to the safety and security of personnel, visitors, patients and facilities during working hours and after hours. Plans are developed and implemented to provide protection from attack, theft or damage to the property.

Criteria

1.7.5.1 Security systems, including guards if required, provide for internal security.

1.7.5.2 Security systems, including guards if required, provide for external security.

1.7.5.3 Sufficient light sources are available to provide adequate light (no dark areas) in all areas such as the entrance, waiting rooms, halls and offices.

1.7.5.4 There is effective control of access to restricted areas in the facility, e.g. medicine store.

1.7.5.5 There is effective control of access to clinical areas and store areas.

1.7.5.6 Alarm systems, if installed and signals are tested every month.

1.7.5.7 A mechanism known to the personnel is available for summoning the assistance of security/police/protection service in the case of an emergency.

1.7.5.8 Reasonable measures are taken to ensure the safety of lone workers.

1.7.6 The practice implements structured systems to ensure fire safety.

Standard Intent:
Fire is an ever-present risk in a practice. As such the practice needs to plan for:

- the prevention of fires through the reduction of risks, such as the safe storage and handling of potentially flammable materials
- safe and unobstructed means of exit in the event of fire
- clearly depicted fire escape routes
- inspection reports from the local fire departments
- suppression mechanisms such as water hoses, chemical suppressants or sprinkler systems

These actions when combined give patients, families, personnel and visitors adequate time to exit the facility safely in the event of a fire or smoke. These actions are effective irrespective of the age, size or construction of the facility.

The fire safety plan for the practice includes:

- the frequency of inspection, testing and maintenance of fire protection and safety systems, consistent with requirements
- the process for testing the plan for the safe evacuation of the facility in the event of a fire or smoke
- a mock evacuation to be carried out at least twice a year
- the necessary education of personnel to protect and evacuate patients effectively when an emergency occurs
- the need for each personnel member to participate in at least one emergency preparedness test per year
- the required documentation of all inspection, testing and maintenance systems

The practice develops and implements a policy and plan to eliminate smoking in the practice's facilities or to limit smoking to designated non-patient care areas.

Criteria

1.7.6.1 There are structured systems and processes in place to ensure that all occupants of the practice's facilities are safe from fire or smoke.

1.7.6.2 Documented certification is available from the relevant authority to show that the facility complies with applicable laws and regulations in relation to fire safety (e.g. fire clearance certificate)

1.7.6.3 Firefighting equipment is regularly inspected and serviced at least annually and the date of the service is recorded on the apparatus.

1.7.6.4 Flammable materials are clearly labelled and safely stored.

1.7.6.5 Sufficient electrical socket outlets are provided in all areas to avoid overloading of individual outlets and to minimise fire risks.

1.7.6.6 Easily recognised and understood signs prohibiting smoking are displayed in areas where flammable materials and combustible gases are stored.

1.7.6.7 A floor plan showing the location of firefighting equipment, electrical distribution board, evacuation routes and emergency exits is displayed.

1.7.6.8 Annual personnel training in fire prevention and evacuation procedures is documented.

1.7.6.9 A mechanism known to the personnel is available for summoning the fire service.

1.7.7 The practice develops a written plan to respond to emergencies.

Standard Intent:
Community emergencies, epidemics and major events such as damage to patient care areas as a result of natural disasters that affects personnel may directly involve the practice. Practices should also be prepared for bomb threats, fire, flooding, natural disasters, explosions and the consequent loss of vital services, failure of water and electrical supplies and hostage taking.

There may be a time when it is necessary to evacuate patients, visitors and personnel. This can only be done quickly and effectively if personnel are trained in evacuation procedures. To respond effectively, the practice develops a plan and rehearses it.

Criteria

1.7.7.1 There is a written plan to deal with emergencies (including bomb threats, fire, flooding, natural disasters, failure of water and electrical supplies).

1.7.7.2 There are site and floor plans that depict the locations and layout of the main services (e.g. water, sanitation, electricity supply).

1.7.7.3 Documented evidence is available to show that the personnel participate in a rehearsal of the plan at least annually.

1.7.7.4 First aid kits and materials for healthcare workers are available.

1.8 Information Management and Quality Improvement

A comprehensive approach to quality management and improvement includes the following:

- planning for improvement in quality
- monitoring how well processes work through indicator data collection
- analysing the data
- implementing and sustaining changes that result in improvement

When performed well, these activities provide the framework for the practice to achieve improvements in quality and safety for patients in areas such as practice structures, systems and clinical care. The data can be gathered from patient or staff feedback, an audit of clinical databases or the analysis of incidents and near misses.

This approach is rooted in the daily work of individual healthcare professionals and other staff members. As GPs/FPs and nurses assess patient needs and provide care, this performance indicator can help them understand how to make real improvements to help their patients. Similarly, managers, support staff and others can apply these standards to their daily work to understand how processes can be made more efficient and resources used more wisely.

The continuous monitoring, analysis and improvement of clinical and managerial processes must be well organised and have clear leadership to achieve maximum benefit. This organised approach considers that most clinical care involves more than one profession. Efforts to improve processes must therefore be guided by an overall framework for quality management and improvement activities in the organisation. These standards address the

full spectrum of clinical and managerial activities of a practice and include the framework for improving those activities and reducing the risks associated with variation in practice.

The framework presented in these standards is suitable for a wide variety of structured processes and less formal approaches to quality management and improvement. It can also incorporate traditional monitoring processes such as those related to unanticipated events (risk management) and resource use (utilisation management).
Over time, organisations that follow this framework will:

- develop greater leadership support for practice-wide processes
- train and involve more staff in monitoring and improvement activities
- set clearer priorities for what to monitor and what to improve
- base decisions on indicator data
- make improvements based on comparison with other organisations, nationally and internationally

1.8.1 The practice has a system to ensure that data and information is made available to meet user needs.

Standard Intent:
To provide co-ordinated and integrated services, practices rely on information relating to individual patients, care provided, results of care and their own performance.

Every practice seeks to obtain, manage and use information to improve patient outcomes as well as individual and overall practice performance. The information management process makes it possible to combine information from various sources and generate reports to support decision making. The combination of clinical and managerial information supports the leaders of the practice to plan collaboratively. Information is also supplied to medical aids to facilitate payments.

Those individuals in the practice who generate, collect, analyse and use the information are educated and trained to participate effectively in the management of information and to understand the need for security and confidentiality of this information.

To facilitate health planning at district, regional and national level, local authorities and the department of health require accurate and complete data from clinicians. Data that is required nationally, such as notifiable diseases, maternal and perinatal mortality statistics, death certificates, etc. are checked for accuracy before leaving the practice and are supplied within the legislated timeframes.

Criteria

1.8.1.1 Clinical, managerial and administrative personnel participate in developing and implementing an information system to support patient care and practice management.

1.8.1.2 Documented procedures which are implemented outline the processes to provide required information to individuals and agencies outside the practice.

1.8.1.3 Clinical and managerial data and information are integrated as needed to support decision-making.

1.8.1.4 Required technology and other resources support the implementation.

1.8.1.5 The practice contributes to external reference databases when required by laws or regulations.

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1.8.1.6 The practice manager or delegated person checks data leaving the facility for completeness, correctness and consistency, including ICD 10 codes supplied to medical aids.

1.8.2 The practice meets the information needs of those who plan and manage the service and those outside the practice who require data and information from the practice.

Standard Intent:
Information that is generated during patient care can be used to safely and effectively managing a practice. The ability to collect and provide information requires effective planning. Planning incorporates input from a variety of sources:

- the care providers
- the administration team
- the practice managers
- those inside and outside the practice who require information about the practice's operational and care processes

The most urgent information needs of those sources influence the practice's information management strategies and its ability to implement those strategies. The strategies are appropriate for the practice's size, complexity of services, availability of trained personnel and other human and technical resources. The plan is comprehensive and includes all the various teams within the practice.
The collection of data is based on the need for information within the practice. The quality improvement programme focuses on, amongst others, patient access, chronic disease management and health promotion activities.

Criteria

1.8.2.1 There is a documented policy for collection, collation, validation and distribution of data which is implemented.

1.8.2.2 The policy has been designed in collaboration with those collecting and using the data.

1.8.2.3 There is a documented policy that defines those permitted access to each category of data and information.

1.8.2.4 The practice collects data relevant to the quality improvement programme for the monitoring and improvement of patient care.

1.8.3 There is a system for the analysis of data.

Standard Intent:
To reach conclusions and make decisions, data must be aggregated, analysed and transformed into useful information. Data analysis is done by individuals with an understanding of information management who also have skills in data aggregation methods and in the use of various statistical tools. To maximise effectiveness, data analysis involves the individuals responsible for the process or outcome being measured. These individuals may be clinical, managerial, administrative or a combination. When implemented in this way,

data analysis provides continuous feedback of quality management information to help those individuals make decisions and continuously improve the process under review.

The practice determines how often data are aggregated and analysed. The frequency depends on the activity or area being measured, the frequency of measurement, and the practice's priorities. For example, clinical data may be analysed once or twice yearly to monitor care in chronic disease management and the performance of contracted services may be analysed quarterly to ensure on-going adequacy of service provision. Aggregation of data at points in time enables the practice to judge a process's stability or an outcome's predictability in relation to expectations. Computers are a useful tool in this process.

The goal of data analysis is to be able to compare a practice in four ways:

- with itself over time
- with other similar health facilities
- with standards
- with evidence based practice and guidelines.

These comparisons help the practice to understand the source and nature of undesirable change and help to focus improvement efforts.

Understanding statistical techniques is helpful in data analysis, especially in interpreting variation and in deciding where improvement is needed. Run charts, control charts, histograms and Pareto charts are examples of statistical tools useful in understanding trends and variations in health care.

Criteria

1.8.3.1 Data is aggregated, analysed and transformed into useful, relevant information for monitoring and improving the service.

1.8.3.2 The frequency of data collection and analysis is appropriate to the process under study.

1.8.3.3 Statistical tools and techniques are used in the analysis process when suitable.

1.8.3.4 Information relating to the quality of the services delivered by the practice is made available to the patients of the practice and other relevant parties.

MANAGEMENT OF QUALITY IMPROVEMENT

1.8.4 The practice appoints an individual or committee which represents all services within the practice to guide the quality improvement process.

Standard Intent:
Leadership and planning are essential if a practice is to initiate and maintain improvement. All leaders participate in establishing the practice's commitment and approach to improvement as well as programme management and supervision.

Improvement programmes are most effective when they are planned practice-wide. The framework for these is provided in a written plan for the programme, which is inclusive of all services in the practice and of all related quality activities such as infection control and risk management activities.

The quality improvement process must:

- be consistent with the practice's mission and strategic plans
- meet the needs of patients, families, staff and other healthcare team members
- use current clinical practice guidelines and other relevant evidence-based information
- include sound business practices
- incorporate relevant risk management information

Leaders and staff prioritise those critical, high-risk, high cost, high volume or problem-prone processes that are most directly related to the quality of care and the safety of the environment. Available data and information are used to identify priority areas.

Participation in data collection and analysis and the planning and implementation of quality improvement programmes require knowledge and skills. Staff receive training consistent with their role in the planned activity. The practice identifies or provides a knowledgeable trainer for this education. Personnel are permitted to attend training as part of their assigned responsibilities. Managerial and clinical personnel participate in the process.

Criteria

1.8.4.1 An individual or committee is appointed to oversee quality management and improvement processes.

1.8.4.2 All practice personal are informed about the appointment and function of the quality management individual/committee.

1.8.4.3 There are formal systems and processes for quality management and improvement.

1.8.4.4 Personnel are trained in the implementation of quality management processes.

1.8.4.5 The leaders allocate resources (including time) for the assessment and improvement of the practice's management, clinical and support processes and this is reflected in the strategic plan/business plan for the practice.

1.8.4.6 The leaders provide technology and support, consistent with the resources of the practice, for tracking and comparing monitoring results.

1.8.4.7 The leaders set priorities for improvement activities based on high risk, high cost and/or high volume or problem-prone areas.

1.8.4.8 Each team within the practice implements relevant quality improvement activities.

1.8.4.9 The objectives, scope, implementation and effectiveness of the activities to assess and improve quality are evaluated regularly and revised as necessary.

1.8.5 Key monitoring, measurement and evaluation processes are planned and implemented.

Standard Intent:
A comprehensive approach to quality management and improvement includes the following processes:

- planning for improvement in quality
- monitoring developments regarding best practice and implementing these as appropriate
- monitoring processes through indicator data collection
- analysing the data
- implementing and sustaining changes that result in improvement

These processes provide the framework for the practice team to achieve ongoing quality improvement thereby assuring their patients of quality care, reflective of current best practice in the rapidly developing world of health care.

The monitoring of clinical and management functions results in the accumulation of data and information. An understanding of how well the practice is doing rests on repeated analysis of the data, information over time and comparison with other practices. The leaders of a practice make the selection of key measures to be included in the practice's monitoring activities.

Criteria

1.8.5.1 Targets (goals) are set for the desired levels of patient care and practice management.

1.8.5.2 Measurable indicators are selected to monitor the quality of important aspects of patient care and practice management.

1.8.5.3 Data are collected for each indicator.

1.8.5.4 As part of clinical monitoring, structured clinical audits are done to monitor the implementation of clinical guidelines.

1.8.6 Analysed data is used to improve the quality of managerial and clinical services.

Standard Intent:
Staff selected to participate in the management and supervision of improvement programmes are those closest to the activities or processes being monitored, studied or improved.

When negative incidents or adverse events occur, the practice and its leaders evaluate the processes that led to the error or event. Faulty processes are redesigned, tested and monitored to ensure that the same or similar errors or events do not occur again.

Case reviews are performed for all new diagnoses of significant, life threatening diseases, unexpected deaths and management of emergency cases that present at the surgery. The routine review of these cases assists in the identification of what went well and what could have been done better to inform continuous improvement in clinical care and enable sharing of best practice.

When the practice detects or suspects an undesirable change from what is expected, it initiates intense analysis to determine where best to focus improvement. In particular, intense analysis is initiated when levels, patterns or trends vary significantly or undesirably from:

- what is expected
- those of other practices or
- recognised standards

Each practice establishes which events are significant and the process for their intense analysis. When undesirable events can be prevented, the practice works to carry out preventive changes.

Criteria

1.8.6.1 Information from the findings of quality assessment and improvement activities is used to detect trends, patterns and opportunities to improve or prevent potential problems.

1.8.6.2 The practice holds regular meetings to discuss significant clinical issues.

1.8.6.3 Information from a validated patient/family satisfaction audit tool is used to improve the quality of service delivery.

1.8.6.4 The tools used to measure patient feedback need to be rigorous to ensure the integrity of data subsequently used by practices for quality improvement purposes.

1.8.6.5 When appropriate an improvement plan is developed in collaboration with all relevant team members and an implementation process agreed.

1.8.6.6 An acceptable timeframe for implementation is agreed by all relevant team members.

1.8.6.7 A time for repeat data collection and analysis is agreed.

1.8.6.8 Repeat data collection and analysis is completed as agreed and the results discussed by the relevant team members.

1.8.7 The practice regularly assesses the quality and the completeness of the patient record content.

Standard Intent:
The clinical record of each patient needs to contain sufficient information to support the diagnosis, justify the treatment provided, and document the care given. Where carry cards are used, there are summaries of each attendance in the service which will provide this information. A standardised format and content of patient's records will help promote the integration and continuity of care among the various providers of care to the patient. The practice determines the specific data and information recorded in the clinical record. Each service has a process to assess the quality and completeness of patient records. This is a part of the performance improvement activities of the practice and is carried out regularly. This information is used to improve the quality of clinical record keeping.
Clinical record review is based on a representative sample of the GPs providing care and of the types of care provided.

Criteria

1.8.7.1 Patient records are reviewed regularly and results analysed as part of the quality improvement process.

1.8.7.2 The review uses a representative sample.

1.8.7.3 Records comply with professionally acceptable norms (including legal requirements where applicable) relating to signature, use of abbreviations and legibility.

1.8.7.4 Standardised diagnosis and procedure codes are used.

1.8.7.5 Symbols and definitions are standardised. Requires MOH feedback.

2 FACILITY MANAGEMENT AND CONTRACTED SERVICES

OVERVIEW OF FACILITY MANAGEMENT AND CONTRACTED SERVICES

Laws, regulations and inspections by national governmental and local authorities determine in large part how a facility is designed, used and maintained. All practices, regardless of their size and resources, must comply with these requirements as part of their responsibilities to patients, families and personnel. Practices begin by complying with relevant laws and regulations. Over time they become more knowledgeable about the details of the physical facility they occupy. They begin to gather data proactively and carry out strategies to reduce risks and enhance the patient care environment.

Buildings, grounds and equipment provided are maintained and do not pose hazards to the occupants. The personnel providing the maintenance service are knowledgeable and competent. Buildings, grounds and utilities are provided and maintained to an acceptable standard in order to ensure that they do not present a risk to the safety and wellbeing of the occupants.

Ensuring that buildings, grounds and utilities are provided and maintained requires that the relevant personnel member/s is/are knowledgeable and competent.

Where service contracts/agreements are awarded to outside agencies, the practice must ensure that there is a written contractual agreement outlining the service and standard of service to be delivered. Contracted agencies must undertake to provide services in accordance with infection control and health and safety requirements. Where applicable the contracted personnel receive training with regard to waste disposal and infection control if this has not been undertaken to a satisfactory level by the contracted company.

2.1 Access to care

2.1.1 Measures are in place to ensure that patient access to the practice is facilitated by adequate infrastructural arrangements.

Criteria

2.1.1.1 Directional signs to the practice are clearly readable and up to date.

2.1.1.2 There is appropriate signage providing information on the services offered by the practice

2.1.1.3 A telephone/emergency number is available and provided to patients on registration and on request.

2.1.1.4 A phone number for the after-hours service of the practice is clearly displayed in the waiting room.

2.1.1.5 Parking is provided close to the building entrance for patients, including the physically challenged.

2.1.1.6 There is wheelchair access to and within the building.

2.1.1.7 Ramps and stairs include safety features such as rails.

2.1.1.8 There are appropriate safety signs in place where access must be restricted. These include, where applicable, all radiation preparation, imaging, treatment and storage rooms, Magnetic Resonance Imaging rooms

2.1.2 Functional facilities are available to provide safety and comfort for patients, personnel and other visitors.

Standard Intent:
In order to provide safe patient care, each unit requires adequate resources. The building is appropriate for a diagnostic imaging practice in terms of size and layout.

The physical facilities required include a reception area, waiting room separate toilet facilities for staff and patients which are adequate for the number of patients seen. Cleaning equipment is safely stored in a room or cupboard used for this purpose only. There is adequate lighting and ventilation.

The rooms housing all imaging and non-imaging diagnostic equipment:
- Has adequate space to facilitate operations, easy movement of staff and patient positioning
- Has sufficient space to accommodate one patient couch, imaging and/or non-imaging equipment and an examiner's chair, at the minimum.
- has adequate lighting
- is maintained at a comfortable temperature suitable to accommodate both patient and equipment requirements.
- ensures patient privacy when the patient needs to undress for a clinical procedure (e.g. the use of adequate curtains or screens and gowns or sheets)

Buildings and grounds are provided and maintained and do not pose hazards to the occupants. The construction of the building; in terms of walls, ceilings, floors, doors and windows; which houses radiation based units and equipment must have the appropriate structural shielding so that doses received by workers and members of the public are kept to the minimum and shall not exceed the respective annual effective doses as prescribed by the Radiation Protection Authority. The general appearance will be examined for neatness, condition of paintwork, signs of leakage, mould spots etc.

Criteria

2.1.2.1 Laws, regulations and other requirements applicable to the practice's facilities are available in writing to the personnel.

2.1.2.2 The building is appropriate as a healthcare facility in terms of size and lay-out.

2.1.2.3 The lay-out of the facility allows for effective flow of patient care.

2.1.2.4 The waiting area is sufficient to accommodate the usual number of patients and other people who could be waiting at any given time.

2.1.2.5 The waiting area caters for the specific needs of children.

2.1.2.6 There is at least one consulting/examination room for every member of the clinical team working in the practice at any time.

2.1.2.7 Sufficient office/administrative space is available for the personnel.

2.1.2.8 All rooms are adequately ventilated.

2.1.2.9 Temperature and ventilation control mechanisms are installed and maintained all rooms housing imaging and non-imaging diagnostic equipment, including invitro and in vivo labs, and other relevant areas.

2.1.2.10 Toilet/washroom facilities are clean and in working order.

2.1.2.11 Separate sanitary facilities are provided for personnel. Requires MOH feedback.

2.1.2.12 There is a separate, secure area for personnel with adequate secure storage facilities for outdoor clothing, handbags and personal possessions.

2.1.2.13 Required furniture and equipment is available according to established lists and functioning properly.

2.1.2.14 Hand washing facilities, including water, soap and paper towels are available for patients and personnel.

2.2 Medical equipment

2.2.1 Medical equipment relevant to the service provided is available and properly maintained to meet the needs of the patient population.

Standard Intent:
Practices are responsible for ensuring that appropriate medical equipment is available and ready for use at all times. There is an accountable, systematic approach to ensuring that cost-effective, safe and appropriate medical equipment is available to meet the demands of quality patient care.

The practice manager takes responsibility for ensuring that medical equipment is available, appropriately maintained and calibrated and that the relevant personnel are competent to use it. The records for maintenance of equipment should include the following as a minimum:

a) Date of service, details and results of the service and the date of the next service
b) Actions taken at the practice in response to the results of the service.

c) A record of the service provider's qualifications do not need to appear on every service report.
d) a record of the service provider's radiation use licence for service and repair (if servicing ionising radiation equipment
e) evidence of successful completion of a recognised service training course appropriate to the equipment being serviced.

Each practice ensures that it has the required equipment which is appropriate to the services offered and the scope of practice of personnel within the facility.

- Blood glucose monitoring equipment
- Disposable syringes and needles
- Equipment for resuscitation, equipment for maintaining and airway (for children and adults) equipment to assist ventilation (including bag and mask), iv access and emergency medicines
- Gloves (sterile and non-sterile)
- Height measurement device
- Oxygen
- Scales
- Sphygmomanometer with small medium and large cuffs
- Stethoscope
- Tourniquet
- Pregnancy testing strips

Criteria

2.2.1.1 A designated individual supervises the management of medical equipment in the practice.

2.2.1.2 There is an inventory medical equipment available at the practice which includes the name of item, manufacturer and serial number (or other identifier).

2.2.1.3 Policies and procedures guide the management of medical equipment.

2.2.1.4 The supply of medical equipment is adequate to meet the needs of the practice.

2.2.1.5 Records are kept of the checking and maintenance of medical equipment.

2.2.1.6 There is a documented procedure known to the personnel for reporting defects in medical equipment.

2.2.1.7 The practice maintains a current inventory of all radiation based equipment which demonstrates that relevant equipment used is registered with the Radiation Protection Board and complies with specifications in the Radiation Protection Act 2006.

2.2.1.8 The practice must demonstrate that all equipment used to acquire, manipulate, print or report images for diagnostic imaging procedures is safe and appropriate for its intended use.

2.2.1.9 Records and service reports, demonstrating the equipment used to provide images are serviced according to manufacturer's guidelines by qualified persons and the requirements of applicable radiation safety legislation. Records should include a)-e) as a minimum.

2.2.1.10 There is either an uninterrupted power supply (UPS), or battery backup system, and an automated voltage stabiliser (AVS) present for critical equipment, which are tested regularly and the results of testing are fully documented

2.3 Maintenance management

2.3.1 The maintenance service is managed to ensure the provision of a safe and effective service.

Standard Intent:
Management ensures that sufficient competent personnel are available to manage routine and emergency functions and meet the needs of a safe and effective health service. Personnel may be in the employ of the practice or be contracted out. Where there are contracted personnel, there must be clearly specified contracts, outlining their roles and responsibilities.

Criteria

2.3.1.1 A designated, competent individual is responsible for supervising the maintenance of buildings, grounds and utilities.

2.3.1.2 Where these services are outsourced the practice personnel have access at all times to a list of these private contractors/service providers with their contact numbers.

2.3.1.3 Written agreements ensure technical back-up services are available at all times during the opening hours of the practice.

2.3.1.4 Written policies and procedures guide practice personnel in the implementation of all service-related requirements e.g. routine maintenance, payment of bills.

2.3.1.5 Basic maintenance equipment and tools are available.

2.3.1.6 Basic technical spare parts are available.

2.3.2 The practice implements a documented preventative planned maintenance programme for buildings, grounds and utilities.

Standard Intent:
The practice plans for regular in-house inspection of facilities to avoid hazards.
Building maintenance includes the monitoring of the following aspects:

a) The general appearance of the inside and outside structure which includes the construction of walls, floors, doors and windows.
b) The condition of the paintwork
c) Water leaks, mould spots
d) Electrical wiring, e.g. exposed wires, switches, electrical sockets
e) Maintenance of the grounds (no litter, neat garden and grass kept short)

Criteria

2.3.2.1 The practice plans and budgets for the upgrading or replacing of systems, buildings or components needed for the continued operation of a safe and effective facility.

2.3.2.2 The practice has a documented preventative maintenance management plan in place.

2.3.2.3 The buildings and grounds are inspected at regular intervals determined by the practice according to a documented policy that includes at least a) to e) listed above.

2.3.2.4 Regular inspections of the facility are documented.

2.3.2.5 There is a documented procedure known to the personnel for reporting defects

2.3.3 ICT equipment is available and properly maintained to meet the needs of the services.

Standard Intent:
The practice is responsible for ensuring that appropriate ICT equipment is available and ready for use at all times. There is an accountable, systematic approach to ensuring that cost-effective, safe and appropriate ICT equipment is available to meet the demands of quality patient care.

Managers take responsibility for ensuring that ICT equipment is available and appropriately maintained and that personnel are competent to use it.

Criteria

2.3.3.1 Policies and procedures guide the management of ICT equipment.

2.3.3.2 A designated individual supervises the management of ICT equipment in the organisation.

2.3.3.3 There is an inventory of all ICT equipment.

2.3.3.4 All desktop and server computers are provided with surge protection and the server is protected by an uninterruptable power supply.

2.3.3.5 A documented policy is available clearly describing appropriate back up procedures for electronic records.

2.3.3.6 Regular checks are made and documented to ensure that backup has been successful.

2.3.3.7 Records are kept of the checking and maintenance of ICT equipment.

2.3.3.8 The practice has appropriate virus protection software and firewall protection to ensure adequate security and confidentiality of patient related information

2.3.3.9 There is documented evidence that relevant personnel are regularly trained to use/operate ICT equipment.

2.4 Cleaning and laundry services

2.4.1 The cleaning and laundry service is managed to ensure the provision of a safe and effective service.

Standard Intent:
Practice managers must ensure that a documented policy is available detailing the cleaning and laundry duties to be undertaken and the frequency with which these need to be performed. Where the cleaning service is outsourced a contract defines the details of the service to be provided.

The practice manager must ensure that facilities and equipment are adequate for the provision of a safe and effective cleaning service.

Criteria

2.4.1.1 A written agreement is available where the cleaning and/or laundry service is outsourced.

2.4.1.2 Written policies and procedures relating to cleaning and laundry duties and the frequency with which these duties are carried out are implemented and monitored.

2.4.1.3 There is evidence that laundry that has been used for patients is washed separately from domestic laundry.

2.4.1.4 Adequate and secure storage areas are available for equipment and chemicals.

2.4.1.5 Chemicals for cleaning and laundry are safely stored out of the reach of patients, children and visitors.

2.4.1.6 There is adequate storage place for brooms and mops.

2.4.1.7 Mops and brooms are cleaned and dried before being stored.

2.4.1.8 Cleaning cupboards are adequately ventilated.

2.4.1.9 The practice manager ensures that cleaning and laundry personnel are appropriately trained regarding waste management, infection control

procedures, confidentiality issues and any other relevant matters.

2.5 Contracted Services

Overview
This section relates to support services that have been contracted to outside agencies, such as cleaning, building maintenance, gardening, IT management, etc. The management and supervision of these services is delegated to one nominated individual who ensures that services comply with criteria relating to management, infection control, environmental safety and health and safety requirements.

2.5.1 Where contracts/service agreements for clinical and/or managerial services exist, these are monitored.

Standard Intent:
Where services are provided through an agreement with an external provider a designated individual is responsible for monitoring these contracts or other arrangements. In all cases the leaders must supervise such written contracts/agreements to ensure that the services meet patient needs and are monitored as part of the quality management and improvement activities.

Criteria

2.5.1.1 Copies of contracts for outside service providers are available to those who ensure they are implemented.

2.5.1.2 Services provided under contracts and other arrangements are formally monitored and compliance with the contract is documented.

2.5.2 There is an adequate number of suitably trained contract personnel to provide a safe and effective service.

Standard Intent:
The practice manager identifies the numbers and types of required personnel for contracted services and defines the desired education, knowledge, skills and any other requirements needed.
Orientation and induction programmes ensure the competence of personnel before they begin to carry out their functions. The personnel act in accordance with job descriptions, and are evaluated in accordance with their assigned responsibilities.
Where appropriate personnel in the employ of the contractor are made aware of issues relating to infection control, waste management, confidential waste and health and safety.

Criteria

2.5.2.1 Contracted personnel are managed as determined in the written service agreement.

2.5.2.2 The practice ensures that contracted personnel are oriented to relevant practice policies and procedures.

2.5.2.3 The practice ensures that contracted personnel participate in relevant practice in-service training programmes (e.g. infection control, health and safety).

3 CLINICAL SERVICES AND PATIENT CARE

3.1 Patient rights

3.1.1 The practice has a patient rights policy.

Standard Intent:
The leaders of a practice are primarily responsible for the way in which that practice treats its patients. The leaders need to know and understand patient and family rights and their practice's responsibilities as specified in laws, charters and regulations. The leaders then provide direction to ensure that personnel throughout the practice assume responsibility for protecting these rights. To protect and advance patient rights effectively, the leaders work collaboratively and seek to understand their responsibilities in relation to the community served by the practice.

Patient and family rights are a fundamental element of all contact between the practice personnel and patients and families. Policies and procedures are developed and implemented to ensure that all personnel are aware of and respond to patient and family rights issues including their role in supporting patients' and families' rights to participate in the care process and the right to the provision of all information requested by patients and families to enable them to do so. The patient's rights policy is appropriate to the patient's age, understanding and language. When written communication is not effective or appropriate, the patient and family are informed of their rights in a manner they can understand.

Criteria

3.1.1.1 Patient and family rights are identified and documented in accordance with relevant and current laws, charters and regulations.

3.1.1.2 There is a patient rights charter which is prominently displayed.

3.1.1.3 The policy includes the right to confidentiality of patient records.

3.1.1.4 The policy includes the right to a second opinion

3.1.2 The practice respects the rights of patients and their families to refuse or discontinue treatment.

Standard Intent:
Patients or those making decisions on their behalf (i.e. in the case of minors or patients who lack mental capacity due to physical or mental illness) may decide not to proceed with the planned care or treatment or not to continue care or treatment after it has been initiated. The practice informs patients and families about their right to make these decisions, about the potential outcomes that could result from these decisions and about their responsibilities related to such decisions. Patients and families are given information on any care and

treatment alternatives. Personnel are informed of their responsibility to implement and respect the choices of patients.

Criteria

3.1.2.1 Patients are informed about their condition and the proposed treatment.

3.1.2.2 The practice informs patients and their families about their rights to refuse or discontinue treatment, and the consequences of such decisions.

3.1.2.3 When patients/carers refuse or discontinue treatment, the consultation regarding their decision is accurately and contemporaneously recorded and includes the details of the discussion regarding the consequences of the decision.

3.1.3 The practice takes measures to protect patient privacy.

Standard Intent:
The practice ensures that the patient's need for privacy is respected, especially when the patient is providing personal information and undergoing clinical examination. Patients may desire privacy from other personnel, other patients and even from family members.

Medical and other health information, when documented and collected in a patient record or other form, is important for understanding the patient, his or her needs and for providing care over time. The practice respects such information as confidential and has implemented policies and procedures that protect such information from loss or misuse. The personnel respect the confidentiality of patient information by not leaving patient files, results, etc. where they might be visible to members of the public and by not holding patient-related discussions where they may be overheard by other patients or visitors. Such carelessness with patient information can result in loss of dignity or employment for the patient and may result in damage to personal or family relationships. These consequences can follow carelessness by the personnel of the practice, or by family members or others not authorised to have access to the information who have obtained information due to the carelessness of personnel.

Criteria

3.1.3.1 The patient's need for privacy is protected during all examinations, procedures and treatments.

3.1.3.2 Patient privacy is protected when providing personal information.

3.1.3.3 The patient's right to privacy is protected for all forms of counselling.

3.1.3.4 Policies and procedures to prevent the loss or misuse of patient information are implemented.

3.1.3.5 When appropriate, patients are permitted to be accompanied by a family member/care-giver during consultations.

3.1.4 The practice has a clearly defined process for obtaining consent.

Standard Intent:

One of the main ways that patients are involved in their care decisions is by granting informed consent. The patient must be provided with all information relating to planned care to enable him or her to make decisions. The consent process is clearly defined by the practice in policies and procedures. Relevant laws and regulations are incorporated into the policies and procedures.

Informed consent for care sometimes requires that people other than or in addition to the patient be involved in decisions about the patient's care. This is especially true when the patient does not have the mental or physical capacity to make care decisions, when culture or custom designate that others make care decisions or when the patient is a child. When the patient cannot make decisions regarding his or her care a surrogate decision-maker is identified. When someone other than the patient gives consent, that individual is noted in the patient's record.

Criteria

3.1.4.1 The practice has a documented policy outlining the procedure for obtaining general consent for treatment.

3.1.4.2 The practice has a documented policy outlining the procedure for obtaining consent prior to a diagnostic/therapeutic procedure being provided.

Guideline Statement:
The policy must ensure that the consent requirements reflect the level of risk attached to each procedure. It is expected that practices obtain written patient consent prior to invasive or high risk procedures. The policy should also include the procedure for patients who are unable to grant consent for themselves by way of age and/or mental/physical incapacity, which is in accordance with the relevant laws and regulations.

3.1.4.3 Documented consent is obtained from patients for health information to be provided to a third party.

3.1.4.4 Where practice members use patient information for research, approval has been obtained from the relevant ethics committee and from patients themselves where required.

3.1.5 The practice informs patients and their families about the processes which it has instituted to receive and act on complaints, conflicts and differences of opinion about patient care and the patient's right to participate in those processes.

Standard Intent:
Patients have a right to voice complaints about their care and to have those complaints reviewed and where possible resolved. Decisions regarding care sometimes present questions, conflicts or other dilemmas for the practice and the patient, family or other decision-makers. The practice has established processes for seeking resolution to such dilemmas and complaints. The practice identifies in policies and procedures those who need to be involved in the processes and how the patient and family participate.

Criteria

3.1.5.1 There is a documented policy outlining the mechanism to allow for the hearing of complaints and how to act upon them.

3.1.5.2 Patients are aware of their right to voice complaints and the processes by which to do so, internally as well as externally where applicable.

3.1.5.3 A nominated individual within the practice is responsible for managing the complaints and ensuring that the complaints policy is implemented.

3.1.5.4 A nominated individual within the practice is responsible to oversee the investigation of and response to the complaint.

3.1.5.5 Complaints are monitored and repetitions or patterns are identified.

3.1.5.6 Any opportunities for improvement identified from the investigation of complaints are implemented.

3.2 Communication with patients and partner services

3.2.1 Patients and partner services in the community are informed of the processes to access the practice services.

Standard Intent:
Patients and services working in collaboration with the practice need to know how and when to contact the practice to access care. It is reasonable to expect most practices to offer care during normal office hours.

For efficiency of service delivery, appointment systems are recommended as best practice.

Criteria

3.2.1.1 Information on services, hours of operation and processes for obtaining care is provided to services in the community who work in collaboration with the practice (e.g. community nursing teams, step down care, allied health professionals etc.)

3.2.1.2 When patients register with the practice they are informed of the opening hours, contact details and after hours care arrangements of the practice.

3.2.1.3 Where the practice has an 'on hold' telephone message, it includes a message for an alternative number to be used in an emergency.

3.2.1.4 The practice renders services based on the needs of the population, but at least during the published operational hours.

3.2.1.5 There is an appointment system for consultations/investigations. – guideline for patients that need prep etc.

3.2.2 The practice has a system for recognising cases requiring more urgent attention and providing patients with longer appointments when appropriate.

Standard Intent:

The practice has a flexible system for determining the order in which patients are seen to accommodate patients' needs for urgent care, non-urgent care, complex care, planned chronic disease management, preventive healthcare and longer consultations.

Members of the practice team should be sensitive to the need for longer appointments when the need for a longer investigation could be anticipated (e.g. when the patient is attending for multiple or complex procedures, chronic disease management).

If the practice is involved in training or research which makes it necessary for third parties to be present during the investigation, the patient is informed of this and given the opportunity to offer or withhold consent.

Criteria

3.2.2.1 There is a system for fast-tracking the very ill, the elderly and frail, and pregnant women.

3.2.2.2 Patients who are waiting are advised of any delays that may be experienced in receiving attention.

3.2.2.3 There is a system to ensure that patients are seen within the shortest possible time.

3.2.2.4 Patients are offered longer appointments when clinically indicated.

3.2.2.5 The patient's consent is obtained if third parties are expected to be present during the consultation.

3.2.3 At registration, sufficient details are taken from the patient to ensure that the patient can be contacted by the practice when necessary and that the clinical team has sufficient background information to provide adequate reports on the clinical findings of the investigation.

Standard Intent:
Accurate contact details are essential in order to follow up results, recall patients for chronic disease monitoring and contact patients or nominated next of kin in emergency situations that may arise. Background medical information is essential to the provision of adequate care, but can be adequately obtained by administrative personnel in the first instance with further detail elicited during the consultation if necessary.

The following details should be obtained at registration of a new patient as a minimum:
a) current address
b) telephone numbers
c) next of kin
d) who to contact in an emergency
e) previous medical history
f) previous surgical history
g) current medication (prescribed and over the counter medications)
h) allergies
i) immunisations
j) health risk factors e.g. smoking, alcohol consumption, physical activity
k) patient signature

Criteria

3.2.3.1 New patients to the practice are asked to complete a form detailing at least a)-k) in the minimum.

3.2.3.2 Patients are asked to update the practice if their contact details change.

3.2.4 Patients are able to obtain advice or information related to their clinical care by telephone and electronic means.

Standard Intent:
Where patients who are known to the practice request information or follow up regarding a condition for which they have previously consulted and the practice team determines that it is clinically safe not to review the patient in a face to face consultation, the patient has access to the relevant information by telephone or electronic communication. The practice has a documented policy regarding such communication that clearly outlines:

a) Limitations of use
b) Positive identification of the patient
c) Timeframe for a response from a clinician
d) That the patient was made aware of any costs involved
e) Documentation of the communication in the patient record

3.2.4.1 The practice implements a policy on telephonic and electronic communication with patients that details at least a) – e) in the standard intent above.

3.2.4.2 There is evidence of practice/patient telephone or electronic advice and information in the patient health records.

3.2.4.3 The practice can demonstrate how it receives and returns telephone and (if applicable) electronic messages from patients.

3.2.5 Patient and family education promotes the concept of taking responsibility for one's own health care.

Standard Intent:
Every patient is offered the information and education he or she requires. All clinical personnel within the practice work collaboratively to provide education in a co-ordinated manner. Personnel collaboration helps to ensure that the information patients and families receive is comprehensive, consistent and as effective as possible.

Education is focused on the specific knowledge and skills the patient and his or her family will need to make care decisions, participate in care and continue care at home. Variables such as educational literacy, beliefs and limitations are taken into account. Each practice decides on the placement and format of educational assessment, planning and delivery of information. Education regarding high risk health issues relevant to the local population is routinely provided by the practice. Standardised materials and processes are used where possible.

Information provided by the practice may include when to resume daily activities, preventive practices relevant to the patient's condition and, when appropriate, information on coping with disease or disability.

Criteria

3.2.5.1 The practice offers relevant health education related to the procedure/investigation to its patients in a planned and consistent manner.

3.2.5.2 Posters and pamphlets are available for commonly performed procedures in the diagnostic imaging practice.

3.2.5.3 Information regarding high risk conditions relevant to the practice population (e.g. HIV, TB, cancer) is visibly displayed and accessible in the waiting room (e.g. posters, pamphlets) and routinely provided to patients during the procedure when appropriate.

3.2.5.4 Relevant patient and family education provided is noted in the patient record.

3.2.5.5 There is documented evidence that patients are referred to these resources, where appropriate.

3.2.5.6 Information is provided in a way and in a language that is understood by those making the care decisions.

3.2.5.7 Prior to a diagnostic imaging procedure being rendered, except in cases of emergency, the practice must ensure that risks regarding the relevant procedure have been advised to the patient or substitute decision maker where necessary:

3.3 Patient records

3.3.1 A system for the storage of health records that meets the needs of confidentiality and safety is implemented.

Standard Intent:
Policies and procedures as well as managerial supervision ensure the safety and confidentiality of files. The policy will define who has access to information, the information to which an individual has access, the user's obligation to keep information confidential and the process followed when confidentiality and/or security are violated. The policy will also make provision for the protection of records against fire, flood, theft and electronic failure.

Personnel members responsible for health record management must have suitable training and experience.

The practice should have policies in place for the safe storage and retrieval of patient files. Files must be readily available each time the patient visits the practice and therefore must be filed in such a way that they are easily identified.

Criteria

3.3.1.1 Designated individuals are responsible for the storage, maintenance and retrieval of patient files.

3.3.1.2 There is a documented policy for the storage and retrieval of patient files.

3.3.1.3 The filing system allows for incorrectly filed records to be easily identified (e.g. through colour coding of the records)

3.3.1.4 Policies and procedures that relate to the safeguarding of information in the record (both paper and electronic) against loss, damage, levels of access for individual staff members, breach of confidentiality or use by unauthorised persons are documented and implemented.

3.3.1.5 A documented policy details how to respond when confidentiality and/or security of the patient records are violated.

3.3.1.6 Storage space for health records is sufficient and secure against unauthorised entry.

3.3.1.7 The designated area for notes storage is out of public view.

3.3.2 The practice has a policy on the archiving, retention and destruction of patient records

Standard Intent:
The practice develops and implements a policy that guides the retention of patient records and other data and information. Patient records and other data and information are retained for sufficient periods to comply with law and regulation and support patient care, the management of the practice, legal documentation, research and education. The retention policy is consistent with the confidentiality and security of such information. When the retention period is complete, patient records and other data and information are destroyed appropriately.

Criteria

3.3.2.1 The practice has a policy on the retention of patient records and other data and information which is implemented.

3.3.2.2 The retention process provides the necessary confidentiality and security.

3.3.2.3 Policies and procedures are developed for health record destruction, specifying the criteria for selection and the method of destruction.

3.3.2.4 Destruction of the record maintains confidentiality of the content.

3.3.3 Patient records contain the required information for the relevant condition.

Standard Intent:
The clinical record of each patient, whether handwritten or electronic, needs to contain sufficient information to support the diagnosis and justify the procedure requested. It also needs to document the investigation performed and the results of the investigation. A standardised format and content of a patient's record will help promote the integration and continuity of care among the various providers of care to the patient. The practice determines the specific data and information recorded in the clinical record but it contains as a minimum for each consultation:

a) relevant information about the patient's health status and individual patient risk factors;
b) The date of the procedure/investigation

c) The clinician/referrers reason for the procedure
d) Name of the radiographer/technologist conducting the procedure
e) Name of the radiologist reporting on the relevant clinical findings, including documenting incidental findings not related to the referring clinician's request but requiring urgent attention.
f) Recommended management plan and, where appropriate, expected process of review
g) Any referral to other healthcare providers or health services
h) Any special advice or other instructions
i) Follow up instructions given to the patient
j) For emergency cases relevant times are recorded, i.e. time patient seen, time drugs administered, etc.
k) Recording of radiation doses(where applicable) received for nuclear medicine and radiotherapy procedures where radiation is administered or received, including the isotope, quantity of radiation, time and date of administration as well as the route of administration.

Guideline and explanation needed here about what specialised information will be required for the different types of investigations

Abbreviations and symbols are standardised. Such standardisation is consistent with recognised local and national standards.
Patient contact details are kept up to date.
All relevant costs are discussed with patients prior to these costs being incurred and the discussion is documented in the patient record.

Criteria

3.3.3.1 Notes for each consultation contain as a minimum points a) – k) above.

3.3.3.2 Handwritten notes are legible.

3.3.3.3 Notes are recorded contemporaneously.

3.3.3.4 All abbreviations are standardised according to recognised local and national standards.

3.3.3.5 The patients' records, including contact details, are up to date to ensure the transfer of the latest information between care providers.

3.3.3.6 There is evidence of review, where applicable, of the results of procedures and diagnostic tests performed by a medical practitioner.

3.3.3.7 Adverse drug reactions are noted in the patient's record.

3.3.3.8 The patient is fully informed regarding the estimated costs of any treatment, investigation, procedure or referral prior to these costs being incurred and the discussion is documented.

3.4 Clinical procedure management

3.4.1 The diagnostic imaging practice must demonstrate that the services provided are only undertaken where there is an identified clinical need which is consistent with best available evidence.

Standard Intent:
Consistency in the approach to diagnosis and management of care among those who are involved in the clinical care of an individual patient is an important aspect of continuity of care. Patients value consistency in the quality of treatment they receive from a practice and expect that treatment and advice given by different physicians within the practice will not be in conflict.
Clinical practice guidelines provide important recommendations for clinical care and should be accessible at the point of care. Practices need to check that clinical guidelines are current.

3.1.1 Criteria

3.4.1.1 The clinical team uses current clinical guidelines relevant to diagnostic imaging practices to assist in the diagnosis and management of patients.

3.4.1.2 The clinical team can demonstrate/describe how they ensure consistency in the pre-procedure, imaging, reporting and recording processes of the diagnostic service.

3.4.1.3 The clinical team can demonstrate how they communicate about clinical issues and support systems in the practice.

3.4.2 The Diagnostic Imaging practice must demonstrate that diagnostic imaging procedures are performed in line with the practice SOP'S and protocols which describes the required projections, a list of anatomy to be visualised, contrast injection requirements and/or positioning required for the acquisition of optimised quality images.

Standard Intent:
A diagnostic imaging practice which uses ionising radiation must ensure that patient radiation exposure is kept as low as reasonably achievable (ALARA) by selecting equipment and techniques for diagnostic imaging procedures sufficient to provide the required clinical information. Documented protocols for routine diagnostic imaging procedures or groups of diagnostic imaging procedures rendered at the diagnostic imaging practice, with evidence that they have been reviewed regularly and follow current best practice guidelines, which include all necessary information for the proper conduct of the examination taking into account any specifications for the required qualifications, experience and specialisation of the personnel. Where specific tasks are delegated to members of the imaging team, the protocols shall indicate any specific circumstances under which personnel shall seek further guidance and/or input from the supervising medical practitioner.

3.6.1 Criteria

3.4.2.1 A technique chart, consistent with the ALARA (as low as reasonably achievable) principle, is available for each unit of ionising radiation equipment located at the diagnostic imaging practice.

3.4.2.2 Where the settings on ionising radiation equipment are entered manually, evidence must be supplied that demonstrates the settings have been reviewed and authorised annually by a qualified person.

3.4.2.3 Where the settings on ionising radiation equipment are embedded in the software and operators select a protocol, evidence must be provided that demonstrates the underlying settings have been reviewed and authorised annually by a qualified person.

3.4.2.4 A copy of a log of screening times for each item of screening fluoroscopy equipment must be provided, and evidence that the log has been reviewed by a qualified person annually.

3.4.2.5 There is evidence for each item of interventional angiography equipment which demonstrates that system generated dose metrics have been logged and reviewed by a qualified person annually. If the interventional angiography equipment is not capable of generating dose metrics, a copy of a log of screening times, and evidence that the log has been reviewed by a qualified person annually should be provided.

3.4.2.6 The practice must establish a program to ensure that radiation doses administered to a patient for diagnostic purposes are annually compared with diagnostic reference levels (DRLs) for diagnostic procedures established internationally.

3.4.2.7 If DRLs are consistently exceeded, they are reviewed to determine whether radiation protection has been optimised.

3.4.3 The diagnostic imaging practice must ensure that all patients are correctly identified and matched to their intended procedure or treatment by:

3.4.3.1 At least three (3) approved patient identifiers are used to match a patient to their request or medical record from the time the patient presents and through all stages of the diagnostic imaging/therapeutic service and when transferring responsibility of care;

3.4.3.2 Relevant personnel correctly match patients with their intended diagnostic imaging/therapeutic procedure

3.4.3.3 Relevant personnel correctly match patients with the correct anatomical site and side (if applicable) of the diagnostic imaging/therapeutic procedure;

3.5 Medication Management

3.5.1 There is a process to ensure the safe and legal prescribing, administration and storage of medication.

Standard Intent:
Medication is administered to patients in the diagnostic imaging department for the purpose of contrast investigations, e.g. Intravenous Pyelograms (IVP), Barium enema, angiography, etc. Where this medication is stored in the department, arrangements must be in place to ensure that these medications are managed in accordance with the practice policy. The diagnostic imaging practice must identify those individuals permitted to order, prepare and

safely administer medication. These individuals must have the knowledge and experience required by law, registration or regulations to be permitted to order medications. The practice must identify any additional individuals permitted to order medications in emergency situations. Medication must be stored in a clean and secure environment that complies with legislation, regulations and professional practice standards. Medications must be clearly labelled, correctly stored and protected from heat, light and moisture where necessary.

NOTE:
A 'medication' in this context refers to anything administered to a patient to create or enhance a diagnostic quality image; and/or where imaging is used as part of an interventional procedure.

A documented policy and procedure describing the procedures for:

a. storing, preparing and disposing of medications as defined above;
b. identifying at risk patients;
c. administering medications safely;
d. monitoring and recording the effects of medication; and
e. reporting, investigating, and responding to adverse reactions or medication mismanagement incidents when they occur.

Criteria

3.5.1.1 The diagnostic imaging practice's protocol and procedure records contain as a minimum points a) – e) above.

3.5.1.2 Where a practice performs examinations using contrast, a documented protocol which ensures the appropriate use and administration of contrast is available.

3.5.1.3 Medication is correctly and safely stored, prepared and disposed of in accordance with manufacturer's guidelines, radiation safety guidelines and relevant regulatory requirements.

3.5.1.4 The scope of and limitations to the responsibilities and activities of the personnel who manage medications are clearly defined in written protocols.

3.5.1.5 Medications, where applicable, are securely and legibly labelled with relevant information as required by practice policy.

3.5.1.6 A register is maintained of all medicines dispensed.

3.5.1.7 The person prescribing and dispensing the medicine has access to patient information that would contra-indicate administration of particular medicines.

3.5.1.8 Documented records of radioactive stocks, calculation and preparation, administration and disposal details are kept.

3.5.1.9 Patients at risk from adverse reactions are identified according to practice policy see also 3.2.9 a-h.

3.5.1.10 Medication is administered safely by a qualified individual, and the effects of medication is actively monitored with all the relevant details recorded in

the patient's records.

3.5.1.11 There is a system/mechanism in place for reporting, investigating and responding to incidents arising from adverse reactions or medication mismanagement.

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3.5.1.12 The patient's medication use and/or history regarding previous reactions to medications relevant to the diagnostic imaging procedures are documented.

3.5.2 Radiopharmaceuticals intended for administration to patients are prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements.

3.5.2.1 Appropriate aseptic precautions are taken.

3.5.2.2 The radio-pharmacy is designed to ensure that the history of each radiopharmaceutical dose can be traced.

3.5.2.3 Radiopharmaceuticals are only dispensed on written request.

3.5.2.4 All details of each Tc-99m generator are recorded, including full details of each elution.

3.5.2.5 Facilities are available for the quality control of all kits reconstituted on the premises.

3.5.2.6 There are separate facilities for the radiolabelling of blood products.

3.5.2.7 Blood products are labelled in a workstation with filtered air (at least a vertical laminar flow unit of biohazard type) to protect the product and designed to protect the operator against contamination.

3.5.2.8 All containers with radioactivity are labelled according to specifications stating that the contents are radioactive and indicating the activity and the date.

3.5.2.9 Administration of all radionuclides for therapy purposes is done in consultation with the physicist and according to statutory radiation safety norms.

3.5.3 The practice has a nominated personnel member who is suitably trained to oversee cold chain management.

Standard Intent:
Medications depend on suitable storage for their potency. In particular, radio pharmaceuticals which are exposed to high ambient temperatures and/or freezing will quickly lose their potency. The cold chain is the system of transporting and storing vaccines within the safe temperature range of 2 - 8°C. For medication to be effective the cold chain must be maintained from the place of manufacture to the point of administration. Each time that vaccines are exposed to the wrong temperature their potency is reduced. To know if vaccines are potent at the time of administration, it is important that they are monitored for exposure to heat and cold as they pass through the cold chain. While domestic refrigerators are not designed to meet the requirements of vaccine storage, safe storage is possible if

healthcare facilities follow simple guidelines. Guidelines may be obtained from the health authorities or from the manufacturers and distributors of vaccines. Foodstuffs must not be stored in the medication refrigerator.

Deep freeze, refrigeration, cold room and cool area facilities are provided for safe storage of certain medications. There is a mechanism for ensuring that the correct temperature is maintained throughout the life of the medications. Deep freezers and refrigerators are defrosted when necessary. Doors, hinges and seals are all functional.

Criteria

3.5.3.1 A dedicated refrigerator is available for those medications requiring storage at low temperatures.

3.5.3.2 A monitoring log is kept of the temperature within the refrigerator and/or cold-chain monitors and is available for inspection at all times.

3.5.3.3 The fridge thermometer is calibrated at regular intervals determined by the practice and the calibration is documented.

3.5.3.4 Any remedial action taken is recorded.

3.5.4 Medications are stored in a secure and clean environment.

Standard Intent:
The practice stores and dispenses medication in a clean and secure environment which complies with laws, regulations and professional practice standards. In particular, medications are clearly labelled, which includes the following:

- generic name
- strength of medicine
- dose, frequency and duration of course
- date of dispensing and expiry date
- name of patient
- name/address of supplier
- child safety warning
- batch number

Secure storage systems ensure that pharmaceuticals and related substances are held under conditions that conform to statutory requirements and manufacturer's requirements.

There are arrangements for ensuring the security of medicines including alarm systems, door access controls and safes/vaults for storing controlled medicines.

There is a registry, log or other mechanism for monitoring and accounting for controlled substances.

Criteria

3.5.4.1 Medication storage areas are protected from heat and light and effectively ventilated.

3.5.4.2 There is a system for ensuring that maximum and minimum stock levels are maintained.

3.5.4.3 Medications are legibly marked and securely labelled.

3.5.4.4 Radiopharmaceuticals are stored in a cabinet of substantial construction, for which only authorised personnel have the keys.

3.5.4.5 Radiopharmaceuticals are stored in suitable facilities which include but are not limited to: lockable storage facilities, ceiling cages, burglar guards and alarm systems with keypads.

3.5.4.6 Radiopharmaceuticals are accurately accounted for in a specific register which is updated contemporaneously and available for inspection at all times.

3.5.4.7 Radiopharmaceuticals that have expired are disposed of in accordance with legal requirements.

3.5.4.8 Hazardous and flammable materials are stored in accordance with relevant regulations.

3.5.4.9 All medicines, or medical consumables are regularly checked for expiry dates and checks are recorded.

3.5.4.10 An inventory management system either manual (stock cards) or automated, is in place and functioning appropriately, e.g. to monitor and control stock losses.

3.6 Results/ Communication with colleagues and the community

3.6.1 The practice has a system for the effective communication of clinical findings, follow up and review of tests and results. (reword)

Standard Intent:
The information gained from diagnostic imaging tests and results can have a considerable impact on the choices patients and their physicians make in patient care. While practices are not expected to track every test ordered, or to contact patients with the results of every test or investigation undertaken, there may be considerable risk in not following up clinically significant tests and results. Where potentially serious pathology is suspected, the practice has a system to track that the investigation is completed and the result is received and acted upon. To minimise clinical risk, results of investigations are reviewed, signed or initialled (or the electronic equivalent), acted on in a timely manner and incorporated into the patient health record.

Written reports must be clear and concise and address the information:

a) requested by the requesting practitioner;
b) required by the diagnostic imaging service; and
c) that is necessary for the interpretation of the images

Many practices provide the results of investigations to their patients by telephone. The person responsible for giving the results should ensure that the recipient of the information is correctly identified using three patient identifiers so that patient confidentiality is not compromised. Acceptable patient identifiers are name, date of birth, address, id number, practice patient number.

Criteria

3.6.1.1 A documented policy on the review and management of imaging reports, and other clinical correspondence received by the practice is implemented.

3.6.1.2 The diagnostic imaging practice effectively communicates the results of a requested diagnostic imaging procedure which includes a)-c) as a minimum.

3.6.1.3 The practice has taken all reasonable steps to advise the requesting practitioner (or another practitioner where necessary) about urgent and unexpected findings.

3.6.1.4 The practice responds to feedback and requests from requesting practitioners about the content or provision of reports and/or advice provided.

3.6.1.5 Where relevant, there are documented quality improvement activities, which describe the actions taken in response to feedback from requesting practitioners.

3.6.1.6 Patient health records contain evidence that all imaging reports and clinical correspondence received by the practice have been handled according to practice policy.

3.6.1.7 There is a system to advise patients of the process for the follow up of results.

3.6.1.8 A documented system to identify, follow up and recall patients with clinically significant results is implemented.

3.6.1.9 When patients are informed of results over the telephone, the patient is identified with 3 approved identifiers before the information is given.

3.6.1.10 When results are given over the telephone, the result is given to the patient themselves or the patient's consent is obtained before giving the result to a nominated third party.

3.6.2 There is a process for appropriate referral of patients for specialised consultation/investigations at other healthcare facilities.

Standard Intent

In some cases, radiologists may refer patients for a secondary consultation to confirm an opinion, or to request more extensive diagnostic evaluations than may be available at the diagnostic imaging practice, or to have patients receive specialised treatment that the referring practice may be unable to provide. The practice must clearly describe the referral process. Practices may wish to consider the use of a standard referral form which includes a tear off slip for the receiving doctor's response following the consultation. The referral should contain the following information:

a) at least three approved patient identifiers
b) relevant history, examination findings and current management
c) known allergies, adverse drug reactions and current medication
d) the name of the referring doctor
e) the name of the doctor/service referred to

f) stated purpose of the referral
g) request for feedback following the consultation with the specialist

Criteria

3.6.2.1 There is a documented process to refer patients.

3.6.2.2 The referral contains a)-f) as a minimum.

3.6.2.3 The lines of communication between the practice, referral centres and community services are clearly defined.

3.6.2.4 The doctor informs the patient if he/she has any financial interest in the referral centre.

3.6.2.5 Referrals are to specific individuals and/or agencies in the patient's home community wherever possible.

3.6.2.6 Patients and as appropriate their families are given follow-up instructions which are provided in an understandable form and manner.

3.6.2.7 A copy of the referral note is available in the patient record.

3.6.2.8 The referral is made on appropriate stationery or electronically.

3.6.2.9 The practice keeps a record of replies received following the referral of patients.

3.6.2.10 There are written guidelines for the referral of emergency patients

3.6.2.11 Follow-up care based on the findings of investigations/consultations performed outside the organisation is noted in the patient record.

3.6.3 The practice engages with a range of health, community and disability services to plan and facilitate optimal patient care.

Standard Intent
Co-ordination of care for individuals, families and communities is part of the accepted definition of a diagnostic imaging and therapeutic service. For patients with complex care needs, e.g. frail elderly, severe disabilities or multiple co-morbidities, practices are encouraged to co-ordinate patient care across the practice setting with other health services including allied health and pharmacy as well as social, disability and community services. It is important for practices to identify relevant services within the local area that can enhance patient care, to have updated registers of such services at hand and to build sound working relationships with these service providers to facilitate good, collaborative care.

Criteria

3.6.3.1 The practice plans and co-ordinates comprehensive care by interaction with other services.

3.6.3.2 Relations are established and contact maintained with other relevant services and agencies, including both governmental and non-governmental agencies.

3.6.3.3 The practice determines that the receiving individual/organisation can meet the patient's continuing care needs, and establishes arrangements to ensure continuity.

3.6.3.4 Individuals responsible for the patient's care and the co-ordination of care are identified for all phases.

3.6.3.5 Patients and as appropriate their families are given understandable follow-up instructions and this is noted in the patient's record.

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3.7 Continuity of care

3.7.1 The practice has an effective clinical handover system that ensures safe and continuing healthcare delivery for patients.

Standard Intent
Clinical handover needs to occur whenever there is an interface of care by different providers.
After-hours care providers are at a disadvantage with regards to specific groups of patients requiring special attention such as the terminally ill. To ensure optimum care provision and a consistent approach from all clinicians, it is to the advantage of both patients and clinicians if relevant information is made available to the clinicians providing after-hours care. To ensure the transfer of this information, the patient is provided with a letter to present to clinicians providing care outside the practice.

Criteria

3.7.1.1 There is a documented policy on clinical handover to ensure that standard processes are followed, which is implemented.

3.7.1.2 Patients share in decision making regarding the handing over of clinical information.

3.7.1.3 Handover of clinical information is recorded in the patients' health records.

3.7.1.4 Information relating to those patients requiring special attention, such as the terminally ill or those with infections which require specific infection control measures, is provided in a patient held letter, a copy of which is kept in the patient record.

3.7.2 The practice ensures safe and reasonable arrangements for medical care for patients outside of normal opening hours in the event of emergency procedures.

Standard Intent
Diagnostic Imaging services outside normal opening hours needs to be provided by recognised practices.
When the Diagnostic Imaging practice cannot safely or reasonably deliver care outside normal opening hours, the practice can clearly document the alternative system of care that

is available for their patients. The practice is responsible for ensuring the alternative care provider offers care to an acceptable standard.

3.7.2.1 There is evidence of one (or a combination) of the following for the patients:

- **The practice's clinicians provide their own service for patients outside normal opening hours, either individually or through a roster;**
- **Formal arrangements for cooperative care outside the normal opening hours exist through a cooperative of one or more local practices;**
- **Formal arrangements exist with a medical deputising (locum) service;**
- **Formal arrangements exist with a local hospital or after hours facility.**

3.7.2.2 Patient health records contain reports or notes of consultations occurring outside normal opening hours by or on behalf of the practice.

3.7.2.3 A message on the practice's telephone answering machine, call diversion system or paging system provide information to patients on how to obtain care outside the practice's normal opening hours.

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3.8 Emergency care

3.8.1 The practice provides emergency treatment and care.

Criteria

3.8.1.1 Written guidelines are available and followed relating to the provision of primary emergency services.

3.8.1.2 Guidelines for paediatric emergency triage, assessment and treatment (ETAT) are available and followed.

3.8.1.3 Information on cases and the outcome of emergency treatment are recorded in a register/logbook.

3.8.1.4 Case reviews are undertaken within the practice to assess the quality of treatment and care of patients requiring emergency care.

3.8.1.5 There is a protocol that delineates how the practice evaluates, manages, stabilises and transfers patients with emergency conditions.

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3.8.2 The practice provides resuscitation in accordance with practice policy.

Standard Intent:
Practices in urban areas with adequate emergency service cover may prefer not to have defibrillators or emergency drugs on site, but are still required to be proficient in the provision of basic life support when necessary. The level of service provided by the practice is agreed by all clinical personnel and documented in a policy.

For practices that offer advanced life support, local paramedics can be consulted on necessary drugs and equipment.

Criteria

3.8.2.1 The practice has a policy on resuscitation, which includes the level at which resuscitation is provided, by whom and training and equipment requirements.

3.8.2.2 The policy includes the availability of resuscitation equipment and medicines with clear instructions for use.

3.8.2.3 All practice personnel are trained in basic resuscitation techniques at least every two years, with records of their attendance at such training.

3.8.3 Equipment for resuscitation is available in accordance with the policies of the practice.

Standard Intent:
Resuscitation equipment and medication is available according to the practice's policy and protocol. There is access to a defibrillator or automated external defibrillator (AED) within 3 minutes of any patient collapsing. Resuscitation equipment includes at least:

- a bag-mask manual ventilator
- a selection of Guedel airways

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Criteria

3.8.3.1 There is a designated resuscitation area.

3.8.3.2 There is a mechanism for the summoning of medical help in an emergency.

3.8.3.3 The practice provides resuscitation equipment according to the practices emergency response policy.

3.8.3.4 Equipment as listed in the standard intent above for early cardiopulmonary resuscitation is available within one minute in each area of the practice.

3.8.3.5 The practice has access to Ambulance Services (EMS).

4 RADIATION SAFETY

4.1 Radiation safety management systems

4.1.1 A radiation safety programme is in place, followed and documented.

Standard Intent
The hospital has an active radiation safety programme appropriate to the risks and hazards encountered. The programme addresses safety practices and prevention measures for radiation personnel, other personnel, patients and members of the public. Where the practice is within the setting of a hospital, the programme is coordinated with the hospital's safety management programme. The radiation safety programme includes:

- Documented policies and procedures which support compliance with applicable standards, laws and regulations
- Documented policies and procedures for the handling and disposal of infectious and hazardous materials

- The availability of safety protective devices appropriate to the practices and hazards encountered
- The orientation of all nuclear medicine personnel to safety procedures and practices
- In-service education for new procedures and newly-acquired or recognised hazardous materials

Criteria

4.1.1.1 A radiation safety programme is in place and is appropriate to the risks and hazards encountered.

4.1.1.2 The programme is coordinated with the hospital's safety management programme.

4.1.1.3 Documented records of radioactive stocks, calculation and preparation, administration and disposal details are kept.

4.1.1.4 A register is kept of sealed sources.

4.1.2 A suitably qualified radiation safety officer is responsible for managing the radiation safety programme.

Standard intent
The diagnostic imaging service must be under the direction of an individual who is qualified by virtue of documented training, expertise and experience, in accordance with applicable laws and regulations. This individual must assume professional responsibility for the implementing the radiation safety programme
The radiation safety officer's responsibilities should include:

- Developing, implementing and maintaining policies and procedures relating to the radiation safety programme
- Maintaining any relevant quality control programmes
- Monitoring and reviewing all radiation safety incidents
- Supporting and advising personnel in the event of radiation incidents.

Criteria

4.1.2.1 A radiation technologist/medical physicist, who is qualified by education, training and experience, manages the radiation safety programme.

Guideline Statement:
Country-specific requirements need to be taken into consideration and the required evidence can be obtained from various sources such as post specifications, or job description. Where applicable, there should be evidence of registration with the relevant professional body/council.

4.1.2.2 The responsibilities of this person include developing, implementing and maintaining relevant policies and procedures.

Guideline Statement:
These responsibilities should be defined in the job description.

4.1.2.3 The responsibilities of this person include monitoring and reviewing all radiation safety incidents.

4.1.2.4 The responsibilities of this person include maintaining quality control programmes.

Guideline Statement:
The initial commissioning tests should be done by the supplier. Thereafter the routine tests should be carried out by the licence holder or persons appointed by the licence holder. Tests must be carried out in accordance with country-specific legislation, where applicable. When a new unit is installed, acceptance tests must be performed by the supplier.
With regards to regular monitoring, the minimum requirements would be monitoring of the processor, Entrance Skin Exposure (ESE) measurements on diagnostic units, DAP measurements, radiation output repeatability, x-ray tube and generator checks.

4.1.2.5 The responsibilities of this person include supporting and advising personnel in the event of radiation incidents.

4.1.2.6 The responsibilities of this person include monitoring and reviewing all radiation safety incidents.

Guideline Statement:
Monitoring systems which review the effective implementation of the radiation safety programme should be implemented. These can include regular staff meetings, and should also include the quality control and radiation safety aspects

4.1.3 There are documented policies and procedures to guide personnel in all aspects of radiation safety within the practice.

Standard Intent
Documented policies and procedures are essential to guide personnel in the nuclear medicine service in their activities. The existence of documented procedures does not preclude modifications in the best interests of the patient.
Nuclear medicine policies and procedures should be related to the requirements or availability of other services in the hospital environment.

Criteria

4.1.3.1 Documented policies and procedures that address compliance with applicable standards, laws and regulations are implemented.

Guideline Statement:
Policies and procedures should include at least the following:
a) The qualifications of staff,
b) Radiation safety, including radiation safety inspections, signage in the department, the handling and disposal of hazardous material, over-exposure, the wearing of dosimeters, etc,
c) X-rays of pregnant women,
d) Requesting X-rays,

e) Reporting on films including the time frames for reporting, and
f) The availability of emergency drugs and equipment.

4.1.3.2 A copy of the local rules relating to current ionising radiation regulations is available.

Guideline Statement:
Country-specific arrangements will apply. Where the country regulations are silent on the rules, guidelines should be sought from international radiation protection organisations such as the International Commission for Radiation Protection (www.icrp.org).

4.1.3.3 Policies and procedures that relate to limiting the irradiation of patients to levels consistent with medical requirements are implemented. The ALARA (as low as reasonably achievable) principle is applied to the calculation, preparation and administration of radioactive doses.

4.1.3.4 A strict policy on the conditions under which pregnant women may be subjected to a procedure involving radiation exposure is available and implemented.

4.1.3.5 There is a procedure to ensure professional handling of a radiation emergency situation.

4.1.3.6 Policies and procedures that relate to avoiding radioactive contamination, and controlling spread should it occur, are implemented.

4.1.3.7 A documented procedure is available for personnel to follow in the event of radioactive contamination.

4.1.3.8 Policies relating to monitoring the hands, clothing and body of every member of personnel leaving a controlled area are implemented.

4.1.3.9 Policies and procedures are implemented for the reporting of adverse reactions to therapy.

4.1.3.10 Policies and procedures are implemented for clinical trials, where applicable.

4.1.3.11 Policies and procedures that address the handling and disposal of infectious and hazardous materials are implemented.

4.2 Safety of facility and equipment

4.2.1 Testing and maintenance are related to the use of the equipment and its documented history of service.

Criteria

4.2.1.1 The radiation safety programme includes monitoring and follow-up of radiation based equipment.

4.2.1.2 A copy of the most recent radiation safety inspection report is held by the

nuclear physician responsible for the practice, or the medical physics department or the medical physicist.

4.2.1.3 Radiation monitors are calibrated regularly.

4.2.1.4 Values are recorded in a log-book.

4.2.1.5 There is adequate documentation of all testing, maintenance and calibration of radiation based equipment.

4.2.1.6 All linear accelerators are calibrated and subjected to a constancy output on a regular and frequent basis.

4.2.1.7 All radiation based equipment is checked on a daily basis.

4.2.1.8 Regular and frequent quality control procedures (e.g. flood uniformities, centre-of-rotation) are attended to or supervised by the medical physicist.

4.2.1.9 All details of each Tc-99m generator are recorded, including full details of each elution.

4.2.1.10 The accuracy of the computer control of all "After Loading High Dose Rate" units is checked at regular intervals and the results recorded.

4.2.2 The practice ensures the safe, efficient and effective functioning of the service where radiation exposure is concerned. ***(in terms of the facility being conducive)***

Standard Intent
All practice personnel work with the radiation safety officer and the management team to ensure that facilities provide for safety and that they comply with current radiation safety laws and regulations.

Criteria

4.2.2.1 At every entrance to a room where radioactive equipment and material is handled, stored and administered, a radiation warning sign is displayed.

4.2.2.2 Requirements regarding controlled and supervised areas laid down by the Radiation Protection Inspectorate/Board or other authority are implemented.

4.2.2.3 There is a shower available in the event of contamination.

4.2.2.4 Separate toilets for personnel and patients are available.

4.2.2.5 A radioactive spill kit is available within the practice (where applicable) and contains as a minimum: PPE, absorbent sheets for liquid spills, radioactive waste bags/containers, demarcating warning signs, decontamination materials.

4.2.2.6 The radiopharmacy is designed to ensure that the history of each radiopharmaceutical dose can be traced.

4.2.2.7 Facilities are available for the quality control of all radiopharmaceutical kits reconstituted on the premises.

4.2.2.8 There are separate facilities for the radiolabelling of blood products.

4.2.2.9 Blood products are labelled in a workstation with filtered air (at least a vertical laminar flow unit of biohazard type) to protect the product and designed to protect the operator against contamination.

4.2.2.10 All containers with radioactivity are labelled according to specifications stating that the contents are radioactive and indicating the activity and the date.

4.2.3 The required radiation safety devices are made available for use by staff and patients.

4.2.3.1 Appropriate radiation safety devices are available which provide the necessary shielding required for the type of radiation utilised in the service.

4.2.3.2 Contamination monitors are provided.

4.2.3.3 Area monitors are available where necessary.

4.3 Patient and staff safety

4.3.1 The practice implements radiation safety practices relevant to occupational and public exposure.

Criteria

4.3.1.1 The practice ensures that radiation to personnel is kept as low as possible.

Guideline Statement:
Dose levels are monitored for all staff members and investigations done when individual levels are suspiciously high or reach the classified worker limit.

4.3.1.2 All personnel are oriented to all radiation safety procedures and practices as part of the radiation safety programme.

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4.3.1.3 Personnel receive education with regard to new procedures and newly-acquired or recognised hazardous materials.

4.3.1.4 Personal dosimeters worn by personnel comply with the ionising radiation regulations.

4.3.1.5 Signs warning of the dangers of radiation to pregnant and breast-feeding women are prominently displayed.

4.3.2 Radioactive materials(open and sealed sources) intended for administration to, or implantation into patients, are prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements.

Standard Intent
Effective quality control systems are essential to providing the safe use of radioactive materials. Quality control procedures should include:
- Validation of the procedures used
- Daily surveillance of results by suitably qualified personnel
- Rapid corrective action when a deficiency is identified
- Documentation of results and corrective actions

Criteria

4.3.2.1 Appropriate aseptic precautions are taken.

4.3.2.2 Radiopharmaceuticals and radioactive implants are only dispensed or prepared on the written request of a qualified medical practitioner.

4.3.2.3 Each preparation of sealed sources is recorded with the dose plan, calculations and all relevant details.

4.3.3 The management of organ disease using open radionuclides is practised, taking into account the safety and well-being of patients and personnel as a consequence of the high radiation levels.

Standard Intent
Where open radionuclides are used, all personnel and patients in the hospital must be protected from exposure to radiation by following established guidelines which are formulated by experts in the field. Supervision should ensure that the guidelines are adhered to.

Criteria

4.3.3.1 The administration of all radionuclides for therapy purposes is done by a qualified nuclear medicine physician or radiation oncologist in consultation with a medical physicist and according to statutory radiation safety norms..

4.3.3.2 Where radioactive material administered to the patient exceeds a level of 370 MBq (10mCi), it is administered by the nuclear physician or radiation oncologist only.

4.3.3.3 Where radioactive material administered to the patient exceeds a level of 370 MBq (10mCi), there is an en-suite ward approved by the medical physicist for the isolation of the patient.

4.3.3.4 In the event that the approved ward is not available, any alternative ward for the isolation of the patient receiving therapy is also approved by the

medical physicist.

4.3.3.5 A radiation survey of the ward used for the isolation of the patient and adjacent areas is conducted according to the requirements of the physicist immediately after the administration of the radioactive material.

4.3.3.6 The isolated patient is monitored regularly during the isolation period.

4.3.3.7 On discharge of the patient who has been isolated, the ward, the bedding and the bathroom are monitored according to the requirements of the physicist.

4.3.3.8 Orally administered radio-iodine 10mCi and above is always in capsule form.

4.3.3.9 Radioiodine by injection is administered only by the nuclear physician or radiation oncologist.

4.3.3.10 Fume hood is used if liquid radioiodine is being prepared and the personnel preparing the radioiodine are adequately protected.

4.3.3.11 Administration of all radionuclides for therapy purposes is done in consultation with the physicist and according to statutory radiation safety norms.